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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,437	07/05/2001	Veronique Barban	MBHB00-1260	7649

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,437	BARBAN, VERONIQUE	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *7-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 09 October, 2003, wherein group I (claims 1-6) was elected with traverse. Applicant contends that a special technical feature is present, namely the peptides of claims 1-6. This argument is clearly not persuasive. As previously set forth, the inventions listed as Groups I-X do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The claims are directed toward multiple products (e.g., peptides, conjugates, vaccine compositions, expression vectors) and methods of use (e.g., detection methods, therapeutic methods) which fail to share a special technical feature. All of the identified products have different structural and functional properties. Moreover, the various methodologies identified are directed toward different scientific objectives and employ different reagents and protocols. Accordingly, a special technical feature is not present. Claims 7-23 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statement filed 07 December, 2001, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 112, Second Paragraph

1. Claims 1-6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The reference to an "anti-HIV" peptide is vague and indefinite. First, it is not readily manifest if the claims are directed toward HIV-1, -2, or both -1 and -2 peptides. Second, the reference to an "anti-HIV" activity is vague and indefinite since the precise functional characteristics of the peptides are not readily manifest. For instance, are the peptides competitive inhibitors of a normal biochemical or functional activity (e.g., inhibitors of gp120-CD4 binding, inhibitors of CD4-gp120 fusion) or do the peptides induce an immune response (e.g., gp120-specific CTL or neutralizing Ab response) against HIV-1? Third, the claim suggests the peptides are actually obtained from an "HIV-positive patient". However, perusal of the disclosure appears to suggest otherwise. It appears that the peptides are not obtained directly from patient samples, but rather are produced in a recombinant peptide library and identified by screening with a Mab that recognizes conformational epitopes on the HIV-1 envelope. Thus, the peptides appear to be recombinant HIV-1 Env mimotopes, not actual patient-derived peptides. Appropriate clarification and correction are required. Applicant should amend the claim language to clearly and unambiguously set forth the salient structural and functional characteristics of the peptides (i.e., An isolated and purified HIV-1 mimotope selected from the group of peptides consisting of SEQ ID NO.: 1, …, and SEQ ID NO.: 11).

35 U.S.C. § 112, First Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

2. Claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims are broadly directed toward a large genus of peptides of poorly defined structure. As set forth *supra*, many of the characteristics of the claimed peptides are confusing. In any event, it appears that the claims are directed toward HIV-1 mimotopes that correspond to conformational epitopes in the HIV-1 envelope glycoprotein. The broadest claim fails to set forth any structural criteria identifying the molecular determinants modulating the critical activities of any given peptide. Thus, the skilled artisan cannot readily envisage any particular from amino acid sequence from the broadly claimed genus.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19

U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of "anti-HIV" peptides. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. **A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest.** *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). **A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.** See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). **The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.**

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are

sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. **The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely.** In the latter case, **disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement.** *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The claims fails to meet the written description requirement as follows:

- The broadest claim only contains poorly phrased functional language. The claim limitations do not impart any specific structural characteristics to any given peptide.

- While the disclosure provides a generic screening method for the identification of mimotopes, it does not allow the skilled artisan to readily envisage the structure of any given mimotope.

- The broadly recited claim language does not lead the skilled artisan to any particular amino acid sequence.

- The disclosure fails to provide a strong correlation between the molecular determinants modulating the "anti-HIV" properties of any given peptide. Thus, the skilled artisan cannot predict the structure of any given mimotope.

Accordingly, the skilled artisan would reasonably conclude that applicant was not in possession of the claimed invention at the time of filing.

Scope

3. Claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for the broad genus of peptides presently claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are broadly directed toward a large genus of peptides of poorly defined structure. As set forth *supra*, many of the characteristics of the claimed peptides are confusing. In any event, it appears that the claims are directed toward HIV-1 mimotopes that correspond to conformational epitopes in the HIV-1 envelope glycoprotein. The broadest claim fails to set forth any structural criteria identifying the molecular determinants modulating the critical

activities of any given peptide. Thus, the skilled artisan cannot readily envisage any particular amino acid sequence from the broadly claimed genus.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

- The disclosure fails to provide adequate guidance pertaining to the molecular determinants modulating the antiviral activities of any given peptide. First, the claim language fails to clearly specify the antiviral properties of any given peptide. Thus, the skilled artisan has been left to guess as to what the actual biochemical or functional properties of any given mimotope may be (i.e., inhibition of gp120-CD4 binding, inhibition of viral entry). Second, the disclosure fails to clearly identify those minimal molecular determinants that are responsible for modulating such activities.

- The disclosure fails to provide adequate structural guidance pertaining to those HIV-1 or -2 amino acids that comprise a conformational epitope. Thus, the skilled artisan has once again been left to guess as to which portions of the Env these proteins mimic.
- The state of the art concerning the identification and preparation of antiviral mimotopes is one of unpredictability. The skilled artisan cannot reasonably predict the final structure of any given peptide. While the disclosure provides a generic screening method, this method fails to provide any illumination on the amino acid sequence of any given peptide.
- The claims are of considerable breadth and are broadly directed toward any antiviral peptide with the poorly defined functional limitations.

Thus, the skilled artisan would reasonably conclude that undue experimentation would be required to practice the invention in a manner commensurate in scope with the claims.

Correspondence

4. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Art Unit 1648

08 February, 2004